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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,521	11/01/2001	Timothy Samuel Girtton	760-35 CIP	6660

7590 11/15/2006  
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EXAMINER

PATTERSON, MARC A

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/002,521

Applicant(s)

GIRTON ET AL.

Examiner

Marc A. Patterson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 21, 22, 24, 25 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 21, 22, 24, 25 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

**WITHDRAWN REJECTIONS**

1. The 35 U.S.C. 103(a) rejection of Claim 26 as being unpatentable over Yen et al (U.S. Patent No. 4,906,377) in view of Verona et al (U.S. Patent No 5,776,185) and Kidd et al (U.S. Patent No. 6,770,202 B1), of record on page 2 of the previous Action, is withdrawn.
2. The 35 U.S.C. 103(a) rejection of Claims 1 and 21 as being unpatentable over Cabasso et al (U.S. Patent No. 4,951,381) in view of Kidd et al (U.S. Patent No. 6,770,202 B1), of record on page 3 of the previous Action, is withdrawn.
3. The 35 U.S.C. 103(a) rejection of Claims 2 – 3, 22 and 24 – 25 as being unpatentable over Cabasso et al (U.S. Patent No. 4,954,381) in view of Kidd et al (U.S. Patent No. 6,770,202 B1) and further in view of Chuter (U.S. Patent No. 6,293,969), of record on page 5 of the previous Action, is withdrawn.

**NEW REJECTIONS**

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Landi (U.S. Patent No. 5,141,522).

With regard to Claims 3 and 25, Landi discloses a PTFE extrudate (column 1, lines 48 – 58) comprising a PTFE resin and a polymeric component which is extractable therefrom to create pores in the PTFE resin which upon implantation permit tissue ingrowth (column 1, lines 48 – 58); the polymeric component is solid (polymethylmethacrylate; column 1, line 19), and is particulate and distributed throughout because pores are created, as stated above; Landi does not disclose a node and fibril structure or an expanded PTFE, and therefore discloses a non – expanded PTFE having no node and fibril structure.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Landi (U.S. Patent No. 5,141,522).

Landi discloses an extrudate having particles as discussed above; the extrudate is tubular (column 1, line 57) and is a medical device (vascular graft; column 1, lines 49 – 50). Landi fails to disclose a particle size of 5 to 100 microns. However, Landi discloses pores which permit tissue growth as discussed above. Therefore, one of ordinary skill in the art would have recognized the utility of varying the particle size to obtain the desired ingrowth. Therefore, the

ingrowth would be readily determined by through routine optimization of the particle size by one having ordinary skill in the art depending on the desired use of the end product as taught by Landi.

It therefore would be obvious for one of ordinary skill in the art to vary the particle size in order to obtain the ingrowth, since the ingrowth would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end result as shown by Landi.

8. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chau et al (U.S. Patent No. 4,874,568).

With regard to Claim 24, Chau et al disclose an extrudate comprising a resin and a polymeric component which is extractable therefrom to create pores in the resin (column 3, lines 5 – 11); the polymeric component is solid (film – forming; column 3, lines 58 – 60), and is particulate and distributed throughout because pores are created, as stated above; the resin is a fluorocarbon (column 3, line 63); Chau et al therefore disclose the use of PTFE, which is the simplest fluorocarbon polymer; Chau et al does not disclose a node and fibril structure or an expanded PTFE, and therefore discloses a non – expanded PTFE having no node and fibril structure; Chau et al do not disclose components other than the resin and polymeric component, and Chau et al therefore disclose an extrudate consisting essentially of the resin and polymeric component; the extrudate consists essentially of PTFE, as stated above, and therefore is implantable; Chau et al fail to disclose pores that permit tissue growth. However, Chau et al disclose the selection of leaching medium, and therefore pore size, depending on the desired use

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of the end product (column 6, lines 36 – 40). Therefore, one of ordinary skill in the art would have recognized the utility of varying the pore size depending on the desired use of the end product.

9. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landi (U.S. Patent No. 5,141,522) in view of Nagasawa (U.S. Patent No. 5,723,526).

Landi discloses a device comprising PTFE and polymethylmethacrylate as discussed above. With regard to Claims 1 and 3, Landi fails to disclose an interpenetrating polymer network.

Nagasawa teaches PTFE (column 2, line 16) that is an interpenetrating polymer network (column 5, lines 9 – 12) for use in the making of a device (article; column 1, lines 13 – 20) for the purpose of obtaining a device that is superior in impact resistance (column 1, lines 13 – 20). One of ordinary skill in the art would therefore have recognized the advantage of providing for the PTFE of Nagasawa in Landi, which comprises a device, depending on the desired impact resistance of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for an interpenetrating polymer network in Landi in order to obtain a device that is superior in impact resistance as taught by Nagasawa.

10. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Landi (U.S. Patent No. 5,141,522) in view of Trescony et al (U.S. Patent No. 5,607,464).

Landi discloses a vascular graft comprising PTFE and a second polymer as discussed above. Landi fails to disclose a polymer comprising silicone.

Trescony et al teach a vascular graft (column 2, lines 50 – 53) comprising PTFE and silicone (column 5, lines 37 – 42) for the purpose of obtaining a vascular graft having kink resistance (column 4, lines 35 – 37). One of ordinary skill in the art would therefore have recognized the advantage of providing for the silicone of Trescony et al in Landi, which comprises PTFE, depending on the desired kink resistance of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a silicone in Landi in order to obtain a vascular graft having kink resistance as taught by Trescony et al.

11. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chau et al (U.S. Patent No. 4,874,568) in view of Trescony et al (U.S. Patent No. 5,607,464).

Chau et al discloses an extrudate comprising PTFE and a second polymer as discussed above. Chau et al fails to disclose a polymer comprising silicone.

Trescony et al teach an extrudate (column 5, line 4) comprising PTFE and silicone (column 5, lines 37 – 42) for the purpose of obtaining an extrudate having kink resistance (column 4, lines 35 – 37). One of ordinary skill in the art would therefore have recognized the advantage of providing for the silicone of Trescony et al in Chau et al, which comprises PTFE, depending on the desired kink resistance of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a silicone in Chau et al in order to obtain an extrudate having kink resistance as taught by Trescony et al.

12. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Landi (U.S. Patent No. 5,141,522) in view of Nagasawa (U.S. Patent No. 5,723,526) and further in view of Chuter (U.S. Patent No. 6,293,969)

Landi and Nagasawa disclose a porous PTFE comprising extractable polymeric material as discussed above. With regard to Claim 2, Landi and Nagasawa fail to disclose a radially distensible stent positioned axially about the tubular extrudate.

Chuter teaches a porous PTFE (PTFE membrane material; column 2, lines 49– 53) comprised in first and second stents (first and second stent graft components; column 2, lines 45 – 47) with one stent positioned about the other stent (the stent components are at different levels, one below the other; column 2, lines 28 – 29) for the purpose of obtaining a stent which is biologically inert (column 2, lines 49 – 53). One of ordinary skill in the art would therefore have recognized the advantage of providing for the stent of Chuter in Landi and Nagasawa, which comprises PTFE, depending on the desired inertness of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a stent, therefore radially distensible, positioned axially about the tubular extrudate in Landi and Nagasawa in order to obtain a stent which is biologically inert as taught by Chuter.



ANSWERS TO APPLICANT'S ARGUMENTS

13. Applicant's arguments and amendments regarding the 35 U.S.C. 102(b) rejection of Claim 26 as being anticipated by Yen et al (U.S. Patent No. 4,906,377) as evidenced by Verona et al (U.S. Patent No 5,776,185), 35 U.S.C. 103(a) rejection of Claims 1 and 21 as being unpatentable over Cabasso et al (U.S. Patent No. 4,951,381) in view of Yen et al (U.S. Patent No. 4,906,377), 35 U.S.C. 103(a) of Claims 2 – 3, 22 and 24 – 25 as being unpatentable over Cabasso et al (U.S. Patent No. 4,951,381) in view of Yen et al (U.S. Patent No. 4,906,377) and further in view of Chuter (U.S. Patent No. 6,293,969), of record in the previous Action, have been considered and have been found to be persuasive. The rejections are therefore withdrawn. The new rejections above are directed to amended Claims 1 – 3, 21 – 22, 24 – 25 and 27.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc A Patterson whose telephone number is 571-272-1497. The examiner can normally be reached on Mon - Fri 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Marc Patterson* 11/13/06

Marc A. Patterson, PhD.

Primary Examiner

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